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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,976	04/02/2007	Flemming Kjaergaard Christensen	PATRADE	7548

7590 12/28/2011

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EXAMINER	
MI, QIUWEN	

ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
12/28/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,976	CHRISTENSEN, FLEMMING KJAERGAARD	
	Examiner	Art Unit	
	QIUWEN MI	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *21-42* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *21-42* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment in the reply filed on 12/6/2011 is acknowledged, with the cancellation of Claims 1-20; and the additional newly added Claims 21-42. Claims 21-42 are pending. **Claims 1, 8, and 13-20 are examined on the merits**.

Any rejection that is not reiterated is hereby withdrawn.

It is noted that in the last office action, it was Kuiyou who taught rooibos tea extract, not Tokumaru et al, Applicant is correct to point that out.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21-27, 41, and 42 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Tokumaru (JP 09191852 A), in view of Kujiyou (JP 07039339 A).

This is a new rejection necessitated by the Applicant's amendment filed on 12/6/2011.

Tokumaru et al teach the health foods contain fermented milk as a main ingredient, Ca salts and oligosaccharides as active ingredients, and .gtoreq.1 foods selected from nucleic acid foods, shark cartilage, Chlorella, collagen, Agaricus blazei, champignon extract, mulberry tea, Tochu (Eucommia ulmoides) tea, Tochu-ginseng tea, Tencha, multivitamins, Fe, soybean

peptides, Angelica keiskei, Aloe, and Gymnema as supplementary ingredients (see Abstract). Tokumaru et al teach lyophilization powder of a kefir contains 100g cow's milk calcium powder; 0.5 g chain oligosaccharide powder (thus fillers and coating agents); 4 g DNA powder extract; powder of a 1.5 g shark fin extract (thus a solid deep sea fish extract, thus contains proteins, thus an active components, thus about 100-1600 mg, thus claim 23 is met); the end of 0.2 g angelica dried powder, and health food obtained 4.5 g (thus ancillary agents) [0047]. Tokumaru et al teach the health food of this invention may be in the form of a tablet (thus contains one or more fillers or ancillary agents conventionally used in the formulation of tablets pharmaceutical composition, thus for oral administration), etc. [0035]. Tokumaru et al teach with Eucommi-ulmoides bark and ginseng radix tea, effects such as cosmetics, recovery from fatigue, aging prevention, and beautiful skin effect are given (thus daily dosage for cosmetic treatment of the skin) [0042] (machine translation was provided). Tokumaru et al teach the chondroitin which is proteoglycan is contained in the shark cartilage. The chondroitin has the function to combine a cell and tissue and to hold moisture, exists in the skin, a blood vessel, a cornea, etc. mostly, and commits living body defense, maintenance of the rhythm of condition, prophylaxis, recovery, aging prevention, etc. [0017] (thus shark cartilage is an active component for aging prevention and beautifying skin effect). Tokumaru et al teach vitamins can use the commercial item which made the one pack ten or more sorts of vitamins, such as a vitamin B group, vitamin C (thus claims 41 and 42 are met), and vitamin D, for this invention [0027].

Tokumaru et al do not teach the incorporation of rooibos extract; neither do Tokumaru et al teach the claimed amount of rooibos extract or deep sea fish extract in claim 24, or the protein content of deep sea fish shark cartilage.

Kujiyou teaches the method for preparation Rooibos Tea (Aspalathus linearis, REDBUSH tea, ROOIBOSCHTEA, taste tea, Leguminosae) extract comprises selecting fresh or dry branches and leaves of Rooibos tea, fermented product or mixture thereof as raw material, and extracted with 2-200 wt. times of water solvent with pH of 7-12 at 40-100.degree.C for 15 min to 4 hr to obtain Rooibos tea extract. The extract obtained by this method has high content of polyethylene phenol materials such as flavonoid and tannin, and can be used as materials of beverage or health food. The pH of the extractive solution is regulated with base such as sodium hydroxide and sodium bicarbonate or basic salt. The Rooibos tea extract has effects in caring skin, strengthening body, relieving allergy, skin and viscera diseases, scavenging free radicals, resisting aging, resisting oxidation, and preventing cancer (thus an active component) (see Abstract). Tokumaru et al teach the rooibos tea extract is extremely excellent in palatability, and has wide range of fields such as health food and drink [0030] (machine translation was provided).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to incorporate rooibos tea from Kujiyou into the health food tablet of Tokumaru et al since Kujiyou teaches rooibos tea extract is extremely excellent in palatability, and has wide range of fields such as health food. It would also have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to incorporate rooibos tea from Kujiyou into the health food of Tokumaru et al since Kujiyou teaches the Rooibos tea extract has effects in caring skin, and resisting aging effect. Therefore, one of the ordinary skills in the art would have been motivated to incorporate rooibos tea from Kujiyou into the health food of Tokumaru et al to enhance its aging prevention, and skin-beautifying effect.

With regard to the claimed amount of rooibos, deep sea fish, or the protein content of deep sea fish, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975

(1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). see MPEP § 2144.05 part II A. Although the prior art did not specifically disclose the claimed amount of rooibos, deep sea fish, or the protein content of deep sea fish, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine all operable and optimal concentrations of rooibos. For instance, the amount of rooibos extract in the health food could be determined by the concentration of the extract, the extraction method of the extract, or the harvest season of the plant. The amount of rooibos extract in the health food could also be varied according to the skin condition of the subject. Furthermore, although Tokumaru et al do not explicitly teach the protein content of shark cartilage, since Tokumaru et al teach shark cartilage has aging preventing effect, thus the concentration of shark cartilage is a result-effective variable, which should be varied according to the condition of the subject's skin. Since Applicant does not limit the concentration or the amount of deep sea fish in the composition, the protein content of the deep sea fish would not actually significantly limit the composition.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant argues that "However, the tablet of Tokumaru is comprised of materially different active ingredients than what is required in the present invention. *See* Tokumaru, paragraph [0001] (stating field of the invention drawn to composition "without starting [sic] the

health food which gives the health effect to a human body, and [without] impairing the flavor of a milk fermentation product"); *see also* id., paragraph [0036] (stating active ingredient of a milk fermentation product principally comprised of calcium slat and oligosaccharides). Therefore, Tokumaru is at best cited for the teaching of a tablet having the flavor of a milk fermentation product" (page 6, 3rd paragraph).

This is not found persuasive. First of all, Tokumaru et al teach the chondroitin which is proteoglycan is contained in the shark cartilage. The chondroitin has the function to combine a cell and tissue and to hold moisture, exists in the skin, a blood vessel, a cornea, etc. mostly, and commits living body defense, maintenance of the rhythm of condition, prophylaxis, recovery, aging prevention, etc. [0017]. Thus shark cartilage is an active component for aging prevention and beautifying skin effect. Secondly, the current claims use open language "comprising", thus it does not preclude containing other active ingredients.

Applicant argues that "However, Kujiyou does not teach the limitation required in claim 21 of the present invention - *i.e.,* an extract of rooibos (Aspalathus linearis) in a range of about 5 to 40 mg" (page 7, 3rd paragraph from the bottom).

This is not found persuasive. Although the prior art did not specifically disclose the claimed amount of rooibos, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine all operable and optimal concentrations of rooibos. For instance, the amount of rooibos extract in the health food could be determined by the concentration of the extract, the extraction method of the extract, or the harvest season of the

plant. The amount of rooibos extract in the health food could also be varied according to the skin condition of the subject.

Claims 21-27, 41, and 42 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Strumor et al (US 6,149,939), in view of Kato et al (JP 05246866 A).

This is a new rejection necessitated by the Applicant's amendment filed on 12/6/2011.

Strumor et al teach a tablet (thus for oral administration, thus containing one or more fillers or ancillary agents conventionally used in the formulation of pharmaceutical composition) for aiding memory comprising 200 mg of shark cartilage (thus a solid extract of a deep sea fish comprising protein, thus as active component, thus claim 23 is met), 150 mg Vitamin C (thus claims 41 and 42 are met), and 15 other components with total weight of the tablet at 2281 mg (col 8, Example II).

Strumor et al do not teach the incorporation of rooibos, neither do Strumor et al teach the claimed amount of rooibos, deep sea fish extract, or the protein content of deep sea fish extract.

Kato et al teach a therapeutic agent for stimulating cerebral metabolism and improving cerebral function contains Aspalathus linearis extract as effective component. The extract is obtained by extracting the leaves or stems of Aspalathus linearis belonging to Leguminosae with water and/or an organic solvent such as methanol, ethanol or acetone to get the Extract. The extract is mixed with conventional medicinal carrier, excipient, binder (thus one or more fillers or ancillary agents), and diluent, and prepared into granule, powder, hard capsule, elastic capsule, syrup, suppository, and injection. The preparation containing Aspalathus linearis

extract can be used for stimulating brain metabolism of mammals including human, improving memory and brain function, treating or improving brain and nervous diseases such as senile dementia and Parkinson disease, without side effect (see Abstract) (machine translation is attached).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to incorporate rooibos tea from Kato et al into the tablet of Strumor et al since Kato et al teach rooibos tea extract is effective in improving memory. Therefore, it would also have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to incorporate rooibos tea from Kato et al into the tablet of Strumor et al to enhance its memory aiding effect.

With regard to the claimed amount of shark cartilage, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. For instance, the amount of shark cartilage extract in the tablet could be determined by the concentration of the extract, or the extraction method of the extract.

With regard to the claimed amount of rooibos extract, deep sea fish extract, or the protein content of deep sea fish extract, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine

experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). see MPEP § 2144.05 part II A. Although the prior art did not specifically disclose the claimed percentage of rooibos extract, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of rooibos extract because concentrations of the claimed rooibos extract are art-recognized result effective variables because they have the ability to improve memory, which would have been routinely determined and optimized in the pharmaceutical art. Furthermore, although Strumor et al do not explicitly teach the protein content of shark cartilage, since Applicant does not limit the concentration or the amount of deep

sea fish in the composition, the protein content of the deep sea fish would not actually significantly limit the composition.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant argues that "However, Strumor does not teach the limitations required in the present invention as claimed. Claim 21 requires, among other features, the limitation of a solid extract of a deep sea fish comprising protein, the protein extract being in a percentage range of about 15-70 wt. %" (page 9, 2nd paragraph).

Although Strumor et al do not explicitly teach the protein content of shark cartilage, since Applicant does not limit the concentration or the amount of deep sea fish in the composition, the protein content of the deep sea fish would not actually significantly limit the composition.

Applicant argues that "Kato is cited for teaching a therapeutic agent for stimulating cerebral metabolism and improving cerebral function. 9/6/2011 Office Action, p.8. The disclosure of Kato asserts that the preparation containing Aspalathus linearis extract can be used for stimulating brain metabolism of mammals including humans, improving memory and brain function, treating or improving brain and nervous diseases such as senile dementia and Parkinson disease, without side effects. JP 05246866 A ("Kato"), Abstract" (page 9, 3rd paragraph).

This is not found persuasive. What is being claimed is a composition, not a method of use. It would have been *prima facie* obvious for one of ordinary skill in the art at the time the

invention was made to incorporate rooibos tea from Kato et al into the tablet of Strumor et al since Kato et al teach rooibos tea extract is effective in improving memory. Therefore, it would also have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to incorporate rooibos tea from Kato et al into the tablet of Strumor et al to enhance its memory aiding effect.

Claims 21-33, 41, and 42 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Tokumaru and Kujiyou as applied to claims 21-27, 41, and 42 above, and further in view of Hetherington et al (CA 2358158 A1).

This is a new rejection necessitated by the Applicant's amendment filed on 12/6/2011.

The teachings of Tokumaru and Kujiyou are set forth above and applied as before.

The combination of Tokumaru and Kujiyou does not specifically teach the incorporation of bearberry into the composition; neither the combination teaches the claimed amount of bearberry, or the weight of the tablet.

Hetherington et al teach use of specific plant extracts for inhibiting elastase activity and for preserving tissue elasticity (see Title). Hetherington et al teach use of Arctostaphylos uva-ursi (bearberry), etc. for inhibiting elastase activity in an animal (see Abstract). Hetherington et al teach in some aspects of the invention, the inhibition of elastase may be adopted to preserve tissue elasticity by decreasing the breakdown of elastin. Examples of tissues on which the tissues on which the elastase inhibitors of the invention may be effective are skin and lung tissue (page 7, 3rd paragraph).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to incorporate bearberry from Hetherington et al into the tablet of Tokumaru et al since Hetherington et al teach bearberry extract is effective in inhibiting elastase. Therefore, it would also have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to incorporate bearberry from Hetherington et al into the tablet of Tokumaru et al to enhance its aging prevention, and skin-beautifying effect.

With regard to the claimed amount of bearberry in the tablet, although the prior art did not specifically disclose the claimed bearberry, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of bearberry because concentrations of the claimed bearberry are art-recognized result effective variables because they have the ability to inhibit elastase, which would have been routinely determined and optimized in the pharmaceutical art. With regard to the claimed weight of the tablet in claim 33, different physical properties of the active ingredients in the tablet require different types and different amounts of excipients, which would result in different weight of the tablet. Also, different administration frequency would also affect the weight of each tablet. The result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claims 21-39, 41, and 42 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Tokumaru, Kujiyou, and Hetherington et al as applied to claims 21-33, 41, and 42 above, and further in view of Ohata et al (JP 2001114634 A) and Shimomura et al (JP 06279255 A).

This is a new rejection necessitated by the Applicant's amendment filed on 12/6/2011.

The teachings of Tokumaru, Kujiyou, and Hetherington et al are set forth above and applied as before.

The combination of Tokumaru, Kujiyou, and Hetherington et al does not specifically teach the incorporation of horsetail extract and shellfish extract into the composition.

Ohata et al teach catalase-protecting agent and antiaging composition containing them (see Title). Ohata et al teach to provide a catalase protecting agent capable of inhibiting aging of skin due to erasing hydrogen peroxide imparting a large effect on aging of skin (see Abstract). Ohata et al teach the catalase protective agent according to claim 1 or 2 being a field horsetail (see Claim 3). Ohata et al teach the constituent according to claim 4 being foodstuffs or a cosmetic (see claim 5).

Shimomura et al teach to obtain a hyaluronidase inhibitor, consisting essentially of a substance prepared by hydrolyzing a mucilage of shellfishes, having lubricity and softness of the skin and capable of preventing bacterial infection and aging (see Abstract). Shimomura et al teach many years internal use of this invention is carried out to the foodstuffs of other purpose, drugs, etc., it mains the lubricity of the skin, and plasticity using the substance in which safety was guaranteed, controls the activity of the hyaluronidase which decomposes the hyaluronic acid

which prevents aging, and relates to the hyaluronidase inhibitor which prevents small JIWA and the dryness of the skin [0001].

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to incorporate horsetail from Ohata et al into the tablet of Tokumaru et al since Ohata et al teach horsetail is capable of inhibiting aging of skin. Therefore, it would also have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to incorporate horsetail extract from Ohata et al into the tablet of Tokumaru et al to enhance its aging prevention, and skin-beautifying effect.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to incorporate shellfishes extract from Shimomura et al into the tablet of Tokumaru et al since Shimomura et al teach shellfishes extract is effective in causing lubricity and softness of the skin and capable of preventing bacterial infection and aging. Therefore, it would also have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to incorporate shellfishes extract from Shimomura et al into the tablet of Tokumaru et al to enhance its aging prevention, and skin-beautifying effect.

Regarding to the claimed amount of horsetail extract and shellfish extract, although the prior art did not specifically disclose the amounts of each constituent, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentrations of the claimed horsetail extract and shellfish extract are art-recognized result effective variables because they have the ability for preventing aging, which would have been routinely determined and optimized in the pharmaceutical art.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claims 21-27, 35-38, 41, and 42 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Tokumaru and Kujiyou as applied to claims 21-27, 41, and 42 above, and further in view of Ohata et al (JP 2001114634 A).

This is a new rejection necessitated by the Applicant's amendment filed on 12/6/2011.

The teachings of Tokumaru and Kujiyou are set forth above and applied as before.

The combination of Tokumaru and Kujiyou does not specifically teach the incorporation of horsetail extract into the composition.

Ohata et al teach catalase-protecting agent and antiaging composition containing them (see Title). Ohata et al teach to provide a catalase protecting agent capable of inhibiting aging of skin due to erasing hydrogen peroxide imparting a large effect on aging of skin (see Abstract). Ohata et al teach the catalase protective agent according to claim 1 or 2 being a field horsetail (see Claim 3). Ohata et al teach the constituent according to claim 4 being foodstuffs or a cosmetic (see claim 5).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to incorporate horsetail from Ohata et al into the tablet of Tokumaru et al since Ohata et al teach horsetail is capable of inhibiting aging of skin. Therefore, it would also

have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to incorporate horsetail extract from Ohata et al into the tablet of Tokumaru et al to enhance its aging prevention, and skin-beautifying effect.

Regarding to the claimed amount of horsetail extract, although the prior art did not specifically disclose the amounts of each constituent, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentrations of the claimed horsetail extract are art-recognized result effective variables because they have the ability for preventing aging, which would have been routinely determined and optimized in the pharmaceutical art.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claims 21-27, and 40-42 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Tokumaru and Kujiyou as applied to claims 21-27, 41, and 42 above, and further in view of Takamatsu (JP 2003055246 A).

This is a new rejection necessitated by the Applicant's amendment filed on 12/6/2011.

The teachings of Tokumaru and Kujiyou are set forth above and applied as before.

The combination of Tokumaru and Kujiyou does not specifically teach the incorporation of diacetyl boldine into the composition.

Takamatsu teaches melanin formation suppressor and inhibitor comprises an extract and/or sap of Geissospermum belonging to Apocynaceae, Turnera belonging to Turneraceae, Ptychopetalum belonging to Olacaceae and/or Peumus belonging to Monimiaceae. Takamatsu teaches the composition is used in skin pharmaceuticals and cosmetics, in foodstuffs for improving fairness of skin and in food additives for maintaining quality of foodstuffs (all claimed) and for preventing liver spots, blotches and freckles of skin. Takamatsu teaches the melanin suppressor and inhibitor improves fairness of skin, prevents liver spots, blotches, freckles of skin and also prevents color change in foods, such as blackening in shrimps, crab, freshly cooked noodles and fruits. The melanin suppressor and inhibitor has good stability and maintains quality of foodstuffs and cosmetics. Takamatsu teaches 50% aqueous ethanol solution (400 g) and Geissospermum sericeum extract (40g) which contained dry solid content (2.8%) were stirred and filtered to obtain a melanin suppressor and inhibitor. The suppressor and inhibitor prevented color-change of foodstuffs, food additive and improved fairness of skin (see Abstract). It is noted that genus Peumus only has one species Peumus boldus, and 50% ethanol could necessarily extract the claimed component diacetyl boldine.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to incorporate diacetyl boldine from Takamatsu into the tablet of Tokumaru et al since Takamatsu teach extract from Peumus is effective in improving fairness of skin. Therefore, it would also have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to incorporate diacetyl boldine from Takamatsu into the tablet of Tokumaru et al to enhance its aging prevention, and skin-beautifying effect.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Qiuwen Mi/

Primary Examiner, Art Unit 1655